FEB 1 2 2004

510(k) Summary

SUBMITTED BY: David Ikeda
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May 05, 2003

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

NAME OF DEVICE:

Trade Name	LIAISON® 25 OH Vitamin D Assay
Common Names/Descriptions:	Automated chemiluminescent immuno-assay for the quantitative determination of 25 OH Vitamin D
Classification Name:	Vitamin D Test System

PREDICATE DEVICE: DiaSorin 25-Hydroxyvitamin D ^{125}I RIA

INTENDED USE: The LIAISON® 25 OH Vitamin D Assay uses chemiluminescent immunoassay (CLIA) technology intended for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated vitamin D metabolites in human serum or plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in an adult population

DEVICE DESCRIPTION: The method for quantitative determination of 25 OH Vitamin D is a direct, competitive chemiluminescence immunoassay (CLIA). Specific antibody to Vitamin D is used for coating magnetic particles (solid phase) and Vitamin D is linked to an isoluminol derivative. During the incubation, 25 OH Vitamin D is dissociated from its binding protein, and competes with labeled Vitamin D for binding sites on the antibody. After the incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of 25 OH Vitamin D present in calibrators, controls, or samples.

TECHNOLOGICAL COMPARISON TO PREDICATE:

Feature	25 OH Vitamin D RIA	LIAISON® 25 OH Vitamin D Assay
Analyte	25-(OH)-D_2/D_3	25-(OH)-D_2/D_3
Intended Use	FOR *IN VITRO* DIAGNOSTIC USE. This kit is intended for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated vitamin D metabolites in human serum or plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in an adult population	FOR *IN VITRO* DIAGNOSTIC USE. The LIAISON® 25 OH Vitamin D Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated vitamin D metabolites in human serum or plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in an adult population
Antisera	Polyclonal specific for 25-(OH)-D_2/D_3	Polyclonal specific for 25-(OH)-D_2/D_3
Tracer	^{125}I radiolabeled 25-(OH)-D analog	Chemiluminescent ABEI labeled 25-(OH)-D analog
Standards	Five concentrations, human serum based, extracted identically to controls and patient samples	Stored Master Curve based on 10 points, derived from serum based standards extracted identically to controls and patient samples
Kit Controls	Two levels, human serum based, extracted identically to standards and patient samples	Two levels, horse serum based, extracted identically to patient samples

PERFORMANCE DATA: A summary of performance data is shown below.

Parameter	Performance Results
Sensitivity (analytical)	< 2.0 ng/mL
Sensitivity (Functional)	7.0 ng/mL
Total Precision (%CV)	6% - 13%
Recovery (mean)	109% ± 18%
Linearity	$y = 0.98x + 4.1$; $r = 0.98$
Endogenous Substance Interference	No significant interference observed at the following concentrations: Bilirubin (30 mg/dL); hemoglobin (250 mg/dL); Cholesterol (125 mg/dL); Triglycerides (1000 mg/dL)
Sample Types	Serum and EDTA Plasma are equivalent
Reference Range	9.5 to 52.0 ng/mL

Analytical sensitivity was tested for three lots of materials, giving values less than 2.0 ng/mL for each lot (1.7 ng/mL; 1.6 ng/mL; and 1.5 ng/mL respectively). Functional sensitivity was determined from serial dilutions as 7.0 ng/mL. Total precision was determined to be 6% to 13%CV across the range of the assay according to NCCLS

guidelines. Samples diluted linearly with a correlation coefficient of 0.98. Serum and EDTA plasma matrices gave equivalent results. The 25 OH Vitamin D in samples stored at 2°C – 8°C for up to 5 days gave equivalent results to fresh samples. Samples subjected to up to 5 freeze/thaw cycles also gave equivalent results to fresh samples. No carry-over was observed in testing low concentration samples directly after high concentration samples. The LIAISON® method correlated well with the DiaSorin RIA method, with a correlation coefficient of 0.88. The reference range established using 98 samples from apparently healthy normal volunteers, collected in the southwestern United States in late autumn, was 9.5 ng/mL to 52.0 ng/mL (2.5^{th} to 97.5^{th} percentiles)

CONCLUSIONS: These data demonstrate the safety and effectiveness of the LIAISON® 25 OH Vitamin D Assay for its intended *in vitro* diagnostic use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 12 2004

Mr. David M. Ikeda
Manager, Regulatory Affairs & Quality Systems
Diasorin, Inc.
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P.O. Box 285
Stillwater, MN 55082-0285

Re: k032844
Trade/Device Name: Liaison® 25-OH Vitamin D Kit
Liaison® Control 25-OH Vitamin D
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D test system
Regulatory Class: Class II
Product Code: MRG; JJX
Dated: January 6, 2004
Received: January 7, 2004

Dear Mr. Ikeda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K032844

Device Name: LIAISON® Control 25 OH Vitamin D

Indications for Use:

The LIAISON® Control 25 OH Vitamin D Set is intended for use as assayed quality control materials to monitor the accuracy and precision of the LIAISON® 25 OH Vitamin D immunoassay.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use: ✓ OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032844

Indications for Use

510(k) Number (if known): K032844

Device Name: LIAISON® 25-OH Vitamin D Kit

Indications For Use:

This kit is intended for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated vitamin D metabolites in human serum or plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in an adult population.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032844